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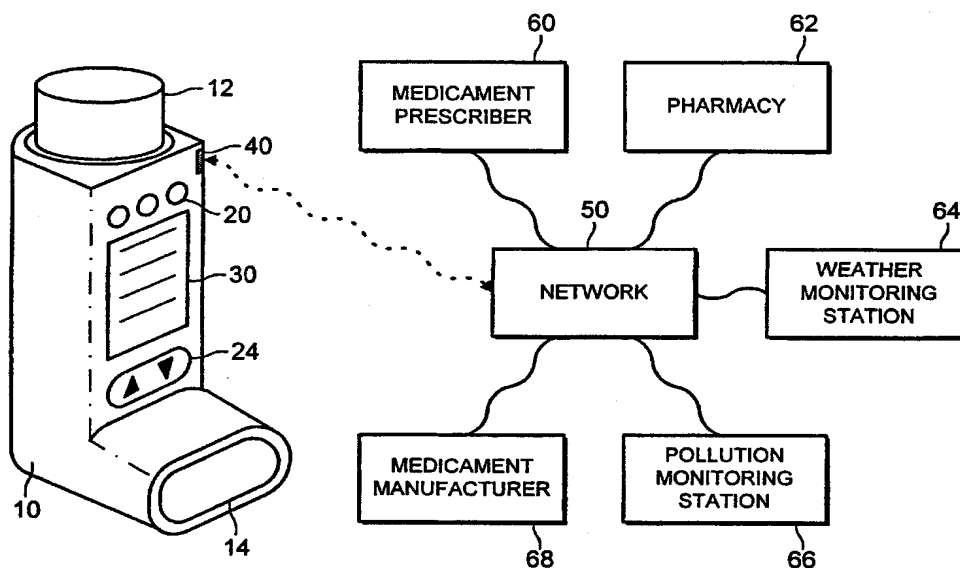
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(54) Title: REMOTE PATIENT ASSESSMENT SYSTEM



(57) Abstract: There is provided a system for the remote assessment of a patient's medical condition comprising a network computer system (50) having specifiable network addresses; remote from said network computer system (50), a patient electronic data collection system (10) for locally collecting data relevant to the patient's medical condition; a communicator (40) for wirelessly communicating with an endpoint to said network computer system (50) to enable transfer of said data to the network computer system (50), wherein the data includes a patient identifier; and a secure access gateway enabling authorised users only to access the data at the network computer system (50).



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**Remote patient assessment system**

5 The present invention relates to a system for the remote assessment of the medical condition of a patient. The system has an electronic data collection system and is capable of wireless communication with an entrypoint to a network computer system to enable communication of data between the network computer system and the electronic data collection system.

10 It is common prescribing practice for a doctor to prescribe a patient with medicament in a medicament dispenser together with instructions for patient administration of the medicament according to a defined treatment regime. The patient typically therefore, receives instructions relating to the correct use of the dispenser together with recommended dosing amounts, dose intervals and  
15 treatment period. The patient is then trusted to follow the treatment regime as set by the doctor.

A limitation associated with this practice is that the treatment regime is set at the time of prescription and can therefore not account for changes in the patient's  
20 condition over the treatment period. A further limitation associated with this practice is that the onus is on the patient to comply with the doctor's instructions. Occasionally, patients will forget to take the medicament or will vary the treatment regime in an unpredictable manner with possible consequences for the success of the treatment.

25 A variation on the above-described prescribing practice involves the use by a patient of a diagnostic device which enables data relating to their medical condition to be gathered on a regular basis. This data may for example, be collected prior to administration of any medicament and a correct dose amount  
30 calculated on the basis of the diagnostic data. An example of this practice would be that of a diabetic who checks their blood-sugar levels in order to calculate a required dose of insulin.

35 In developments of the practice variation, the diagnostic device may be integrated with the delivery system. Information relating to the patient's condition

and usage of the dispenser may thus be displayed to the patient to enable the better management of their medical condition. The information may further be stored in a memory such that it may be recalled at a later time to enable historic analysis of the progress of the condition and effect of the treatment. Dispensers  
5 employing electronic data management systems have been proposed for this purpose.

US-A-5,363,842 describes an inhalation device for use in delivering inhalable medicament. The device enables data relating to the patient's breathing pattern  
10 to be collected, analysed and displayed to the patient. The data is stored in a memory for download to a workstation at the clinic.

WO99/35588 describes a method for managing the administration of medicine and in particular, monitoring patient compliance with a prescribed treatment  
15 regime. The method relies on input of patient data to a central computer workstation. The central computer workstation calculates and transmits dosage data to a dispensing device via a communications link. The dispensing device delivers drug in accord with the dosage data.

The Applicants have now developed an improved system for the remote  
20 assessment of a patient which employs an electronic data collection system. The system is capable of wireless communication with an entrypoint to a network computer system to enable communication of data between the network computer system and the electronic data collection system. The system  
25 therefore, provides the advantage of enabling transfer of patient assessment data to a network of computers, which network can be made accessible to diverse remote datasources, which may in turn be networked together for cross-transfer of data. The patient and authorised users can therefore, have ready access to patient assessment data and to diverse, possibly inter-connected,  
30 remote information sources capable of providing disease management information. In turn, the system can feed information, such as compliance data, back to any authorised user having access to the network computer system.

The system can be further configured to allow selective access to data  
35 depending upon level of user authorisation. Still further, the system can be

integrated with a system for the provision of electronic prescriptions to enable seamless remote assessment and prescription of medicament or variation of the prescription regime.

5 According to one aspect of the present invention there is provided a system for the remote assessment of a patient's medical condition comprising a network computer system having specifiable network addresses; remote from said network computer system, a patient electronic data collection system for locally  
10 collecting data relevant to the patient's medical condition; a communicator for wirelessly communicating with an endpoint to said network computer system to enable transfer of said data to the network computer system, wherein the data includes a patient identifier; and a secure access gateway permitting access to the data on the network computer system in response to a user authorisation command.

15 The patient electronic data collection system is physically, and potentially geographically distant from the network computer system. In embodiments, it is envisaged that the patient data collection system is designed to be kept under the control of the patient e.g. it may be worn by the patient or be a handheld  
20 device always carried by the patient. Examples of patient-wearable devices would include belt attachable devices, devices in the form of watches for wrist or leg attachment and devices attachable as jewellery. Suitable body attachment means will be incorporated as required.

25 The patient electronic data collection system may in a preferred aspect be integrated with a system for the delivery of medicament. The medicament delivery system will typically comprise a medicament container and a dispensing mechanism for dispensing medicament from the medicament container. In one aspect the medicament delivery system and electronic data collection system  
30 are comprised within a handheld device.

The communicator is local to the patient, for example being integral with the patient data collection system, or within another handheld device or present in the home or working environment of the patient. The communicator may for  
35 example, be in a device which mechanically coupled to a device housing the

patient data collection system by any suitable mechanical mechanism including grip mechanisms and snap-fit mechanisms. In a preferred aspect, the data communicator forms a snap-in module and the device housing the patient data collection system is shaped for receipt of the module.

5

The network computer system by contrast, is typically located at or under the control of a specialist healthcare data manager. The data manager may for example be associated with a healthcare provider or manager such as a doctor's practice, a hospital, a healthcare management centre or a pharmaceutical company. It is an advantage of the system herein, that the network computer system may be located geographically distant from the patient.

10

The network computer system may be comprised on a single hub server or it may be a distributed system comprised on plural associated servers. Network addresses may be specified either on a permanent basis or on a temporary/dynamic assignment basis.

15

The patient data includes an identifier which may be explicit or it may be anonymous in the sense of being invisible in the absence of authorisation to view the identifier. Data may be arranged within the network system in any appropriate fashion. Thus, in one embodiment each patient identifier has a distinct database on the network assigned thereto. In another embodiment, the data is arranged within a single database on the network and data is accessible therefrom either by reference to the identifier or collectively on an anonymous basis (i.e. no reference to a particular patient identifier).

20

25

Embodiments are envisaged herein in which the system comprises or is associated with a system for electronic reward or payment such that the patient may be provided with a reward or payment in return for communicating data to the network computer system. Embodiments are also envisaged in which the system comprises or is associated with a system for electronic billing such that any authorised user may be charged for the right to access data on the network computer system.

30

In one aspect, the patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a regular basis.

5 In another aspect, the patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a continuous basis.

10 Suitably, the patient monitoring system forms part of a compliance monitoring system arranged to monitor patient compliance with a particular treatment regime.

15 Suitably, the patient electronic data collection system forms part of a medicament delivery system and is arranged to collect data when the patient uses the medicament delivery system.

20 In embodiments, the medicament delivery system provides respirable delivery of medicament to the patient or injectable delivery of medicament to the patient or is an implant in the body of the patient.

25 Suitably, the medicament delivery system includes a predictive algorithm or look-up table for calculating the optimum amount of medicament to dispense. Suitably, the medicament delivery system has a memory including a dose memory for storing dosage data and reference is made to the dose memory in calculating the optimum amount of medicament to dispense.

30 Suitably, the medicament delivery system additionally comprises a selector for selecting the amount of medicament to deliver. In one aspect, the selector is manually operable. In another aspect, the selector is operable in response to a signal from a transmitter.

35 Suitably, the system additionally comprises a detector for detecting dispensing from the medicament container, wherein said detector communicates dispensing data to the electronic data management system.

Suitably, the data is communicable between the patient electronic data collection system and the network computer system in encrypted form. All suitable methods of encryption or partial encryption are envisaged. Password protection may also be employed. Other methods of ensuring data security are envisaged including the use of systems reliant on the use of secure token codes.

Either the network computer system or the communicator may initiate data transfer. In one aspect, the communicator enables two-way transfer of data between the network computer system and the electronic data management system.

In one aspect, the data is continuously communicable between the patient electronic data collection system and the network computer system.

In another aspect, the data is communicable in packet form between the patient electronic data collection system and the network computer system.

Suitably, the secure access gateway is password protected.

Suitably, the secure access gateway enables different levels of access authorisation to the data to be assigned to different authorised users.

Suitably, the authorised users are selected from the group consisting of the patient, a healthcare professional such as a doctor or nurse, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof.

Suitably, information from a patient-remote datasource is made available to the network computer system.

In one aspect, the patient-remote datasource comprises data relating to ambient environmental conditions such as weather conditions, or pollution, smog and pollen levels.



In another aspect, the patient-remote datasource comprises a database of prescribable medicaments. The database may be arranged to focus on medicaments of particular applicability to the patient's condition and to be the subject of regular update as new medicaments are released to the market.

5

The patient-remote datasource may, for example be managed by a medicament prescriber, for example a doctor's practice. Information transferred from the medicament prescriber may thus, comprise changes to prescription details, automatic prescription updates or training information. Information transferred to the medicament prescriber may comprise compliance information, that is to say information relating to the patient's compliance with a set-prescribing programme. Patient performance information relating for example, to patient-collected diagnostic data may also be transferred to the medicament prescriber.

10

In another aspect, the patient-remote datasource is managed by a pharmacy. Information transferred from the pharmacy may thus, comprise information relating to the medicament product. Information sent to the pharmacy may thus include prescription requests which have been remotely pre-authorized by the medicament prescriber.

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20

In a further aspect, the patient-remote datasource is an emergency assistance provider, for example a hospital accident and emergency service or an emergency helpline or switchboard. The information may thus, comprise a distress or emergency assist signal which requests emergency assistance.

25

In a further aspect, the patient-remote datasource is a manufacturer of medicament or medicament delivery systems. Information transferred to the system may thus, comprise product update information. The system may also be configured to feed information back to the manufacturer relating to system performance.

30

In a further aspect, the patient-remote datasource is a research establishment. In a clinical trials situation, information may thus be transferred relating to the trials protocol and information relating to patient compliance fed back to the research establishment.

35

Suitably, the patient electronic data collection system further comprises a patient electronic data management system comprising a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data. The memory may comprise a non-volatile memory chip (e.g. an EEPROM or FLASH memory chip) which is capable of storing data when the electronic data collection system is turned off.

Suitably, the patient electronic data management system additionally comprises a geographic positioning system such as a global positioning system or a system which relies on the use of multiple communications signals and a triangulation algorithm.

Suitably, the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system.

Suitably, the system additionally comprises an authorised user data communicator comprising an authorised user electronic data management system comprising a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data; and a communicator for wirelessly communicating with an entrypoint to a network computer system to enable communication of data between the network computer system and the authorised user electronic data management system.

According to another aspect of the present invention there is provided a system for the remote assessment of a patient's medical condition and remote prescription therefor comprising a system as described above and additionally a first authorised user data communicator capable of communicating a prescription authorisation command to the network computer system; and a second authorised user data communicator capable of receiving a prescription authorisation command from the network computer system.

Suitably, any communicator employs radiofrequency or optical (e.g infra red or ultra violet) signals.

5 In one aspect, any communicator communicates with the network computer system via a gateway thereto. Communication will typically involve the use of a suitable communications protocol.

10 In another aspect, the system (device) is provided with an embedded network server to enable it to be comprised directly within the network system, typically using IP protocol. The embedded network server will have hardware and software components and for example comprise an HTTP (web) server, an FTP (file) server or an SMTP (mail) server. The embedded network server will typically be provided with a unique network address such as a web-site address, an e-mail address or a file transfer protocol address. The so-enabled system  
15 (device) may also have the capability to form local area networks with other similarly enabled systems (devices) to enable local transfer of data therebetween.

20 Suitably, the communicator communicates with network computer system via a second communications device. The second communications device may itself comprise an embedded web server. Preferably, the second communications device is a telecommunications device, more preferably a cellular phone or pager. Preferably, the communicator communicates with the second communications device using spread spectrum radiofrequency signals. A  
25 suitable spread spectrum protocol is the Bluetooth (trade mark) standard which employs rapid (e.g. 1600 times a second) hopping between plural frequencies (e.g. 79 different frequencies). The protocol may further employ multiple sending of data bits (e.g. sending in triplicate) to reduce the effect of interference.

30 In another aspect, the communicator communicates with the second communications device using an infra red data communications standard (e.g. IrDA).

35 In one aspect, the network computer system comprises a public access network computer system. The Internet is one suitable example of a public access

network computer system, wherein the entryptment thereto is typically managed by an Internet service provider. The public access network computer system may also form part of a telecommunications system, which may itself be either a traditional copper wire system, a cellular system or an optical or microwave network.

In another aspect, the network computer system comprises a private access network computer system typically comprising a private entryptment system. The private access network system may for example, comprise an intranet or extranet which may for example, be maintained by a health service provider or medicament manufacturer. The private access network system may for example include password protection; a firewall; and suitable encryption means.

Suitably, the communicator enables communication with a user-specific network address in the network computer system. The user-specific network address may be selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address. The network address may be pre-assigned or it may be dynamically assigned at the time of communication.

Suitably, the patient electronic data management system additionally comprises a datalink for linking to a local data store such as a personal computer or set-top box to enable communication of data between the local data store and the microprocessor. Preferably, the datalink comprises an infrared emitter and sensor.

Suitably, the patient electronic data management system additionally comprises a data input system for user input of data to the electronic data management system. More preferably, the data input system comprises a man machine interface preferably selected from a keypad, voice recognition interface, graphical user interface (GUI) or biometrics interface.

Suitably, the patient electronic data management system additionally comprises a display for display of data from the patient electronic data management system to the user. The display may for example, comprise a screen such as an LED or LCD screen.

Suitably, the patient electronic data management system includes a predictive algorithm or look-up table for calculating the optimum amount of medicament to dispense.

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Suitably, the memory includes a dose memory for storing dosage data and reference is made to the dose memory in calculating the optimum amount of medicament to dispense.

10

Suitably, the system additionally comprises a selector for selecting the amount of medicament to dispense from a medicament dispensing mechanism. The selector may thus be employed to vary the medicament dose for dispensing from the dispensing mechanism.

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In one aspect, the selector is manually operable.

In another aspect, the selector is operable in response to a signal from the transmitter.

20

Suitably, the selector comprises a timing mechanism for varying the time interval of actuation of the dispensing mechanism.

Alternatively, the selector comprises a metering mechanism between the medicament container and the dispensing mechanism for metering a variable quantity of medicament for dispensing.

25

Alternatively, the selector comprises a multiple-fire mechanism for multiple actuation of the dispensing mechanism, wherein each actuation releases a portion of the optimum amount of medicament. Successive actuations may be pulsed, for example such that the time intervals between actuations may be based on arithmetic or geometric progressions.

30

Suitably, the system additionally comprises a detector for detecting dispensing from the medicament container, wherein said detector communicates dispensing data to the patient electronic data management system.

35

In one aspect, the system is suitable for the remote assessment of a patient's respiratory condition and additionally comprises a sensor which senses the breath of a user, wherein the sensor communicates breath data to the patient electronic data collection system.

Suitably, the sensor comprises a breath-movable element which is movable in response to the breath of a patient. Preferably, the breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

In another aspect, the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

In a further aspect, the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

In a further aspect, the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. The temperature of the inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool.

In a further aspect, the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. The moisture content of the inhaled and exhaled part of the breath cycle varies and this also may be used as a measurement tool.

In a further aspect, the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user. The chemical profile of the inhaled and exhaled part of the breath cycle varies and this further may be used as a measurement tool.

Suitably, the breath data includes breath cycle data or peak flow data.

In one aspect, the system is suitable for the delivery of respirable medicament and additionally comprises a sensor which senses the breath of a user, wherein

the sensor communicates breath data to the electronic data management system.

5 Suitably, the system additionally comprises an actuator for actuating the dispensing mechanism, said actuator being actuable in response to a trigger signal from the transmitter.

10 Suitably, the electronic data management system includes a predictive algorithm or look-up table for deriving from the breath data when to transmit the trigger signal. For example, a real-time analysis of the patient breath waveform may be made and the trigger point derived by reference to that analysed waveform.

15 In one preferred aspect, the medicament container is an aerosol container and the dispensing mechanism is an aerosol valve.

In another preferred aspect, the medicament container is a dry-powder container, that is to say a container suitable for containing medicament in dry-powder form.

20 Suitably, the actuator comprises an energy store for storing energy which energy is releasable to actuate the dispensing mechanism of the medicament container. The energy store comprises in preferred aspects, a biasable resilient member such as a spring, a source of compressed fluid such as a canister of compressed gas or a battery. Chemical energy sources are also suitable and might include  
25 chemical propellant or ignition mixtures. Other sources might include physical explosives such as liquefied or solidified gas in a canister which burst when heated or exposed to the atmosphere.

30 The system may additionally comprise a safety mechanism to prevent unintended multiple actuations of the actuator. The patient is thereby protected from inadvertently receiving multiple doses of medicament in a situation where they take a number of short rapid breaths. More preferably, the safety mechanism imposes a time delay between successive actuations of the actuator. The time delay is typically of the order of from three to thirty seconds.

35

An actuation counter which can be mechanical or electronic may be provided to the system.

5 A medicament dispensing counter, such as a dose counter, may be provided to the system. This may be mechanical or electronic. The counter may be coupled to a visual display to provide feedback to the patient as to amount of drug released or remaining in the container.

10 A manual override can be provided to the system for use in the event of emergency or system failure.

15 In another aspect, the system is suitable for the remote assessment of a patient's cardiovascular condition and additionally comprises a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system. Preferably, the sensor measures the blood pressure of the patient.

20 According to another aspect of the present invention there is provided a method for remotely assessing a patient's medical condition comprising locally collecting data relevant to the patient's medical condition in electronic form; wirelessly communicating with an entrypoint to a remote network computer system to enable transfer of said data to said remote network computer system; and permitting authorised user access to the data on the remote network computer system via a secure access gateway.

25 Suitably, the method comprises collecting the data on a regular basis.

Suitably, the method comprises collecting the data on a continuous basis.

30 Suitably, the method comprises wirelessly communicating the data in encrypted form.

In one aspect, the data is continuously communicable. In another aspect, the data is communicable in packet form.

35



Suitably, the method comprises permitting different levels of access to the data to different authorised users.

5 In one aspect the method is suitable for remotely assessing a patient's condition and remotely prescribing therefor and additionally comprises a first authorised user communicating a prescription authorisation command to the network computer system; a second authorised user receiving said prescription authorisation command from the network computer system; and said second authorised user preparing the prescription based on the prescription  
10 authorisation.

In another aspect, the method is suitable for remotely assessing a patient's condition and remotely prescribing therefor and additionally comprises a first authorised user (e.g. a doctor) communicating a prescription authorisation  
15 command to a pharmacy network computer system; a second authorised user (e.g. a pharmacist) receiving said prescription authorisation command from the pharmacy network computer system; and said second authorised user preparing the prescription for the patient based on the prescription authorisation. The pharmacy network computer system is arranged for communication with the  
20 network computer system – the communication channel therebetween may be permanently open or may be arranged for communication only when data transfer is required.

Suitably, the first authorised user communicates the prescription authorisation in  
25 response to a 'update prescription' alerting signal visible at the patient-specific network address. The 'update prescription' signal is typically based on data communicated from the patient data collection system which may for example, reflect a change in the patient's condition. In one aspect, where the patient data collection system forms part of a medicament delivery system the 'update  
30 prescription' signal may be an alert that the levels of medicament in the delivery system are running low and that a re-prescription is needed.

The system for electronic prescription may incorporate or be associated with an electronic billing and/or payment system such that a healthcare professional may

be electronically rewarded for authorising or preparing the prescription and the patient may be billed for any services received.

According to a further aspect of the present invention there is provided a network computer system for use with the remote assessment system described above comprising a patient data controller unit capable of receiving patient data in electronic form; associated with said controller unit, a patient database for storing said patient data; a secure access gateway to said patient database permitting access thereto in response to an authorised user command; search means associated with the controller unit for searching said patient database in response to an authorised user inquiry; results transmitting means associated with the controller unit for transmitting the results of said authorised user inquiry to the authorised user. The patient data and the authorised user inquiry originate remotely from the network computer system.

Suitably, the network computer system comprises a web-site or server hub on an Internet or Extranet computer system. The patient data arises from a patient data collection system local to the patient and in wireless communication with an endpoint to the network computer system. The authorised user inquiry originates from any suitable authorised user. The system may be configured to allow for selective access to the patient database dependent upon level of user authorisation.

According to a further aspect of the present invention there is provided a method for receiving patient data and enabling authorised user access thereto comprising receiving patient data in electronic form at an interface (e.g. a patient data controller unit); storing said patient data in a patient database associated with said controller unit; permitting access to said patient database in response to an authorised user command; searching said patient database in response to an authorised user inquiry; and transmitting the results of said authorised user inquiry to the authorised user, wherein the patient data and the authorised user inquiry originate remotely from the patient data controller unit.

Suitably, the patient data is received and access to said patient database is permitted via a network using TCP/IP.

According to a further aspect of the present invention, the method described above may be implemented in the form of computer software. The software may comprise a computer program comprising program code means for, when  
5 executed on a computer, instructing a computer to perform all of the steps of the method. The software may also comprise a computer program product comprising a computer readable recording medium having recorded thereon a computer program comprising code means for, when executed on a computer, instructing said computer to perform the steps of the method.

10 Embodiments of systems according to the invention will now be described with reference to the accompanying drawings in which:

15 Figure 1. is a schematic representation of a first system in accord with the present invention in which the patient electronic data collection system forms part of a medicament delivery system;

20 Figure 2. is a schematic representation of a second system in accord with the present invention in which the patient electronic data collection system forms part of a medicament delivery system;

25 Figures 3. and 4. are schematic representations of third and fourth systems in accord with the present invention in which the patient remote assessment system integrates with a system for electronic prescription of medicament;

Figure 5. is a system diagram of a third system in accord with the present invention;

30 Figure 6. is a system diagram of a central controller unit for use in accord with the present invention;

Figure 7. is a system diagram of a patient electronic data manager for use in accord with the present invention;

Figure 8. is a flow diagram illustrating the steps of data collection and data communication to the network in accord with the present invention; and

Figure 9. is a flow diagram illustrating the steps of data access at the network in accord with the present invention.

Figure 1. shows a standard-form metered dose inhaler for the delivery of inhalable medicament comprising a tubular housing 10 in which an aerosol container 12 is located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. A dispensing outlet 14 leads laterally from the closed end of the housing 10. In the embodiment illustrated, the outlet 14 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

The aerosol container 12 is located in the housing 10 so that one end protrudes from the open top of the housing 10. The aerosol container 12 has an outlet valve stem (not visible) at one end which connects with a support (not shown) in the housing 10. To dispense the dose, the protruding portion of the aerosol container 12 is depressed to move the container 12 relative to the valve stem to open the valve and dispense medicament into the outlet 14 from which it can be inhaled by a patient.

The dispenser includes an electronic data management system in the form of an integrated circuit preferably integrated into one or more integrated circuit chips and comprised within the housing (not visible). The user may access the electronic data management system by use of push-buttons 20 and toggle menu-button 24. Display 30 allows for display of menu choices and data from the electronic data management system. The dispenser communicates via communications transceiver 40 to network computer system 50. The network computer system 50 comprises a secure extranet computer system. Remote information sources 60, 62, 64, 66, 68 also have access to the extranet. In more detail, the remote information sources comprise a medicament prescriber 60, a pharmacy 62, a weather monitoring station 64, a pollution monitoring station 66 and a medicament manufacturer 68. Two-way data transfer is possible between

the electronic data management system and the network computer system 50 via the communications transceiver 40. Information transfer is thus possible between the electronic data management system and any of the remote information sources 60, 62, 64, 66, 68. Information received from any of the remote information sources 60, 62, 64, 66, 68 may be utilised by the electronic data management system to vary the recommended medicament dose for delivery to the patient.

Figure 2. shows a variation of the system of Figure 1. The system comprises standard-form metered dose inhaler for the delivery of inhalable medicament comprising tubular housing 110, an aerosol container 112 and dispensing outlet 114. Operation of the inhaler is as described above with reference to Figure 1.

The dispenser includes an electronic data management and communications system 140 comprised within the housing 110. Display 130 allows for limited display data from the electronic data management system. The dispenser readily communicates via communications system 140 to palmtop computer 170. The communication is via spread spectrum radiofrequency signals operable over a relatively short range (e.g. up to ten metres). The palmtop computer 170 has a more sophisticated display 172 including a graphical user interface comprising menu-entry screens from which selections may be made using toggle menu-button 174.

The patient accesses the electronic data management system 140 of the dispenser through the palmtop computer 170. The palmtop computer 170 itself can communicate through a telecommunications link with network computer system 150. The network computer system 150 comprises a secure extranet computer system. As in Figure 1, remote information sources may also have access to the extranet. Two-way data transfer is possible between the electronic data management system and the network computer system 150 via the communications links with the palmtop computer 170. Information transfer is thus possible between the electronic data management system 140, palmtop computer 170 and any of the remote information sources.

Figure 3 shows a system herein in which patient electronic data collection system 240 communicates wirelessly with geographically distant network computer system 250. The network computer system 250 is itself accessible (e.g. wirelessly or by a modem link) by the system of a medicament prescriber 260 (e.g. a doctor's surgery system) and by the system of a pharmacist 262.

The system of Figure 3 may be employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data collection system 240 communicates data relating to the medical condition of the patient to the network computer system 250. The medicament prescriber 260 accesses this data e.g. by use of a palmtop communications and data management device with wireless communications capability, and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the network computer system 250. The pharmacist 262 then accesses the network computer system to receive the 'prescription authorisation' signal which authorises them to make up the prescription for the patient.

The system of Figure 4 is a variation of the system of Figure 3 in which patient electronic data collection system 340 communicates wirelessly with geographically distant network computer system 350. The network computer system 350 is itself accessible by the system of a medicament prescriber 360 (e.g. a doctor's surgery system). The prescriber system 360 may also access second network computer system 354 which is accessible by the system of a pharmacist 362. In an alternative herein, the second computer system 354 may be integral with the system of the pharmacist 362 or be a dedicated secure prescription system accessible only to the prescriber and the pharmacist.

The system of Figure 4 is employed in the remote assessment of a patient and electronic prescribing therefor as follows. The patient data collection system 340 communicates data relating to the medical condition of the patient to the network computer system 350. The medicament prescriber 360 wirelessly accesses this data and makes a judgement as to prescription needs. If a new prescription is needed the prescriber sends a 'prescription authorisation' signal to the second network computer system 354. The pharmacist 362 then accesses the network

computer system to receive the 'prescription authorisation' signal which authorises the pharmacist to make up the prescription for the patient.

Figure 5. shows a representative system herein comprising an electronic patient data collector 440 which would be under the control of the patient. Associated with the patient electronic data collector 440 there is a patient communicator 442 (e.g. a WAP protocol communicator) which is capable of communication with a network computer system 450. The system also comprises an authorised user interface 480 having associated authorised user communicator 482 which is capable of communicating with the network computer system 450. Central controller unit 490 is in two-way communication with the network computer system 450.

The system of Figure 5. is shown in patient 'data upload mode' wherein patient data 444 is being communicated to the network. It may be appreciated that any patient can also communicate requests for data to the network 450 and receive responses thereto via the patient communicator 442. The system is also shown in authorised user 'enquiry mode' in which a database enquiry 484 is communicated to the network computer system 450 and a response received 486 via the authorised user communicator 482 to the authorised user interface 480.

Figure 6. shows the structure of the central controller 590 in more detail. The central controller includes a data storage device 591, central processor (CPU) 592, cryptographic processor 593, RAM 594, ROM 595, payment processor 596, operating system 597 and billing processor 598.

The components of the central controller 590 must be selected to be capable of handling sufficiently large volumes of data. The data storage devices, processors and operating system and other components may be selected from those commercially available.

The data storage device 591 is partitioned to include plural databases. The databases comprise a patient data database 548 which comprises diagnostic or compliance data communicated from the patient electronic data collector; a

patient database 549 which includes patient details such as name, address and possibly medical history; an authorised user database 589 which includes details of authorised users of the system; a billing database 561 for billing authorised users on retrieval of data; a payment database 563 for payment of patients or other authorised users in return for data provided; and a crypto key database 565 comprising encryption information.

It will be appreciated that various parts of the system are designed to co-operate with each other in use. For example, the cryptographic processor 593 will access the crypto key database 565 to enable performance of user authentication. Together these crypto elements may form a secure access gateway to the patient data database.

Figure 7. shows a patient electronic data collector 610 comprised with a respiratory patient monitoring system (not shown). The electronic data collector 610 comprises a central processor unit (CPU) 621; RAM 622; ROM 623 and a cryptographic processor 624. The CPU 621 receives patient data from sensor 615 which may for example be a breath sensor or a sensor detecting actuation of the monitoring system. The received data is storable in data storage device 625 which includes two databases, one for storage of patient medical data 626 and one for storage of personal patient data 628. The CPU 621 is associated with man machine interface 620 for receipt of patient input commands and display driver 632 and display 630 for display of information to the patient. The CPU 621 is further associated with communications port 640 which links via modem 642 to the central controller 690 of a network computer system (not shown).

It will be appreciated that the basic structure of the patient electronic data collector 610 of Figure 7. can act as an authorised data communicator for making enquiry requests to the databases on the network computer system and receiving responses therefrom. It will also be appreciated that the structure of the patient electronic data collector could be adapted by removal of the sensor 615 to form a non-patient authorised data communicator which would not be comprised within a respiratory monitoring system.



In the flow diagram of Figure 8, the steps involved in a typical data collection and upload procedure are illustrated. Initially a patient activates 702 a data collector system which is located on a respiratory drug delivery system (as in Figure 1). The patient inhales through the mouthpiece 704 and a breath sensor collects data 706 relating to the patient's breath. The patient then actuates the system for drug delivery 708. Actuation may be manually actuated or it may be actuated in response to the patient's inhalation through the mouthpiece 704. An actuation sensor collects actuation data 710, for example relating to the time of actuation and type of drug delivered. The breath and actuation data is collected and processed by an electronic data manager 712. Either automatically, or in response to a request by the patient the communicator dials into the patient network address on the network computer system 712. Before access is permitted user authentication checks 716 are undertaken typically involving a password login. Once access is granted the data is communicated to the network address 718. Once data upload is completed the communications link is closed 720.

In the flow diagram of Figure 9, the steps involved in a typical data search and review procedure are illustrated. Following activation by an authorised user, a communicator dials into the patient network address on the network computer system 822. Before access is permitted user authentication checks 824 are undertaken typically involving a password login procedure. A search interface is browsed 826 by the authorised user in order that search parameters may be selected and a search of the patient database undertaken 828. The results of the search may if download of search results is permitted be communicated to the authorised user 830 for analysis offline. Alternatively, if download of search data is not permitted the system will enable online review of the data at the network address 834. Following either data download or online review the user will exit the system by closing the communications link 832, 836.

The medicament delivery system aspect of the invention is in one aspect suitable for dispensing medicament for the treatment of respiratory disorders such as disorders of the lungs and bronchial tracts including asthma and chronic obstructive pulmonary disorder (COPD).

Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (eg s the sodium salt), ketotifen or nedocromil (eg as the sodium salt); antiinfectives e.g.,

5 cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone (eg as the dipropionate ester), fluticasone (eg as the propionate ester), flunisolide, budesonide, rofleponide, mometasone eg as the furoate ester), ciclesonide, triamcinolone (eg as the acetonide) or 6 $\alpha$ , 9 $\alpha$ -difluoro-11 $\beta$ -

10 hydroxy-16 $\alpha$ -methyl-3-oxo-17 $\alpha$ -propionyloxy-androsta-1,4-diene-17 $\beta$ -carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol (eg as free base or sulphate), salmeterol (eg as xinafoate), ephedrine, adrenaline, fenoterol (eg as hydrobromide), formoterol (eg as fumarate), isoprenaline, metaproterenol, phenylephrine,

15 phenylpropanolamine, pirbuterol (eg as acetate), reproterol (eg as hydrochloride), rimiterol, terbutaline (eg as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; adenosine 2a agonists, eg 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)-

20 tetrahydro-furan-3,4-diol (e.g. as maleate);  $\alpha_4$  integrin inhibitors eg (2S)-3-[4-({[4-(aminocarbonyl)-1-piperidiny]carbonyl}oxy)phenyl]-2-[(2S)-4-methyl-2-{{[2-(2-methylphenoxy) acetyl]amino}pentanoyl}amino] propanoic acid (e.g as free acid or potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (eg as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone,

25 hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine

30 salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as

solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

5 Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

10 Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (eg as the fumarate salt) in combination with an anti-inflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate) or budesonide. A particularly preferred combination is a combination of fluticasone propionate and salmeterol, or a salt thereof  
15 (particularly the xinafoate salt). A further combination of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

20 It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

25 The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

**CLAIMS:**

1. A system for the remote assessment of a patient's medical condition comprising

a network computer system having specifiable network addresses;

remote from said network computer system, a patient electronic data collection system for locally collecting data relevant to the patient's medical condition;

a communicator for wirelessly communicating with an entrypoint to said network computer system to enable transfer of said data to the network computer system, wherein the data includes a patient identifier; and

a secure access gateway permitting access to the data on the network computer system in response to a user authorisation command.

2. A system according to claim 1, wherein said patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a regular basis.

3. A system according to claim 2, wherein the patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a continuous basis.

4. A system according to any of claims 1 to 3, wherein said patient monitoring system forms part of a compliance monitoring system arranged to monitor patient compliance with a particular treatment regime.

5. A system according to any of claims 1 to 4, wherein the patient electronic data collection system forms part of a medicament delivery system and is arranged to collect data when the patient uses the medicament delivery system.

6. A system according to claim 5, wherein the medicament delivery system provides respirable delivery of medicament to the patient.

5 7. A system according to claim 5, wherein the medicament delivery system provides injectable delivery of medicament to the patient.

8. A system according to claim 5, wherein the medicament delivery system is an implant in the body of the patient.

10 9. A system according to any of claims 1 to 8, wherein the data is communicable between the patient electronic data collection system and the network computer system in encrypted form.

15 10. A system according to any of claims 1 to 9, wherein the data is continuously communicable between the patient electronic data collection system and the network computer system.

20 11. A system according to any of claims 1 to 10, wherein the data is communicable in packet form between the patient electronic data collection system and the network computer system.

12. A system according to any of claims 1 to 11, wherein the secure access gateway is password protected.

25 13. A system according to any of claims 1 to 12, wherein the secure access gateway enables different levels of access authorisation to the data to be assigned to different authorised users.

30 14. A system according to any of claims 1 to 13, wherein the authorised users are selected from the group consisting of the patient, a healthcare professional, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof.

35 15. A system according to any of claims 1 to 14, wherein information from a patient-remote datasource is made available to the network computer system.

16. A system according to claim 15, wherein the patient-remote datasource comprises data relating to ambient environmental conditions.

5 17. A system according to claim 15, wherein the patient-remote datasource comprises a database of prescribable medicaments.

10 18. A system according to any of claims 1 to 17, wherein the patient electronic data collection system further comprises a patient electronic data management system comprising

a memory for storage of data;

15 a microprocessor for performing operations on said data; and

a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.

20 19. A system according to claim 18, wherein said patient electronic data management system additionally comprises a geographic positioning system.

25 20. A system according to either of claims 18 or 19, wherein the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system.

21. A system according to any of claims 1 to 20, additionally comprising an authorised user data communicator comprising

30 an authorised user electronic data management system comprising

a memory for storage of data;

a microprocessor for performing operations on said data; and

a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data; and

5 a communicator for wirelessly communicating with an entrypoint to a network computer system to enable communication of data between the network computer system and the authorised user electronic data management system.

22. A system according to claim 21 for the remote assessment of a patient's medical condition and remote prescription therefor comprising

10 a first authorised user data communicator capable of communicating a prescription authorisation command to the network computer system; and

15 a second authorised user data communicator capable of receiving a prescription authorisation command from the network computer system.

23. A system according to any of claims 1 to 22, wherein any communicator employs radiofrequency or optical signals.

20 24. A system according to any of claims 1 to 23, wherein any communicator communicates with the network computer system via a gateway thereto.

25 25. A system according to any of claims 1 to 23, wherein the communicator includes an embedded network server.

26. A system according to any of claims 1 to 25, wherein the communicator communicates with the network computer system via a second communications device having telecommunications capability.

30 27. A system according to claim 26, wherein the telecommunications device comprises a cellular phone or pager.

28. A system according to any of claims 25 to 27, wherein the communicator communicates with the second communications device using spread spectrum radiofrequency signals.

5 29. A system according to any of claims 1 to 28, wherein the network computer system comprises a public access network computer system.

30. A system according to any of claims 1 to 29, wherein the network computer system comprises a private access network computer system.

10

31. A system according to any of claims 1 to 30, wherein the patient-specific network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address.

15 32. A system according to any of claims 18 to 31, wherein the patient electronic data management system additionally comprises a data input system for patient input of data to the electronic data management system.

20 33. A system according to claim 32, wherein said data input system comprises a man machine interface selected from a keypad, graphical user interface (GUI), voice recognition interface or biometrics interface.

25 34. A system according to any of claims 18 to 33, additionally comprising a display for display of data from the patient electronic data management system to the patient.

30 35. A system according to any of claims 1 to 34 for the remote assessment of a patient's respiratory condition additionally comprising a sensor which senses the breath of a user, wherein the sensor communicates breath data to the patient electronic data collection system.

36. A system according to claim 35, wherein said sensor comprises a breath-movable element which is movable in response to the breath of a patient.



37. A system according to claim 36, wherein said breath-movable element is selected from the group consisting of a vane, a sail, a piston and an impeller.

38. A system according to claim 35, wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user.

39. A system according to claim 35, wherein the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user.

40. A system according to claim 35, wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user.

41. A system according to claim 35, wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user.

42. A system according to claim 35, wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user.

43. A system according to any of claims 35 to 42, wherein said breath data includes breath cycle data.

44. A system according to any of claims 35 to 42, wherein said breath data includes peak flow data.

45. A system according to any of claims 1 to 34 for the remote assessment of a patient's cardiovascular condition additionally comprising a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system.

46. A system according to claim 45, wherein said sensor measures the blood pressure of the patient.

47. A method for remotely assessing a patient's medical condition comprising

5 locally collecting data relevant to the patient's medical condition in electronic form;

wirelessly communicating with an entrypoint to a remote network computer system to enable transfer of said data to said remote network computer system;  
10 and

permitting authorised user access to the data on the remote network computer system via a secure access gateway.

15 48. A method according to claim 47, comprising collecting the data on a regular basis.

49. A method according to claim 47, comprising collecting the data on a continuous basis.  
20

50. A method according to any of claims 47 to 49, comprising wirelessly communicating the data in encrypted form.

51. A method according to any of claims 47 to 50, wherein the data is continuously communicable.  
25

52. A method according to any of claims 47 to 50, wherein the data is communicable in packet form.

30 53. A method according to any of claims 47 to 52, comprising permitting different levels of access to the data to different authorised users.

54. A method according to any of claims 47 to 53 for remotely assessing a patient's condition and remotely prescribing therefor additionally comprising  
35

a first authorised user communicating a prescription authorisation command to the network computer system;

5 a second authorised user receiving said prescription authorisation command from the network computer system; and

said second authorised user preparing the prescription based on the prescription authorisation.

10 55. A method according to any of claims 47 to 53 for remotely assessing a patient's condition and remotely prescribing therefor additionally comprising

a first authorised user communicating a prescription authorisation command to a pharmacy network computer system;

15 a second authorised user receiving said prescription authorisation command from the pharmacy network computer system; and

20 said second authorised user preparing the prescription for the patient based on the prescription authorisation,

wherein the pharmacy network computer system is arranged for communication with the network computer system.

25 56. A method according to either of claims 54 or 55, wherein the first authorised user communicates the prescription authorisation in response to a 'update prescription' alerting signal visible at the patient-specific network address.

30 57. A network computer system for use with the system according to any of claims 1 to 46 comprising

a patient data controller unit capable of receiving patient data in electronic form;

associated with said controller unit, a patient database for storing said patient data;

a secure access gateway to said patient database permitting access thereto in response to an authorised user command;

search means associated with the controller unit for searching said patient database in response to an authorised user inquiry;

results transmitting means associated with the controller unit for transmitting the results of said authorised user inquiry to the authorised user;

wherein the patient data and the authorised user inquiry originate remotely from the network computer system.

58. A method for receiving patient data and enabling authorised user access thereto comprising

receiving patient data in electronic form at a patient data controller unit;

storing said patient data in a patient database associated with said controller unit;

permitting access to said patient database in response to an authorised user command;

searching said patient database in response to an authorised user inquiry; and

transmitting the results of said authorised user inquiry to the authorised user,

wherein the patient data and the authorised user inquiry originate remotely from the patient data controller unit.

59. A method according to claim 58, wherein said patient data is received and access to said patient database is permitted via a network using TCP/IP.

60. A computer program comprising program code means for, when executed on a computer, instructing the computer to perform all of the steps of either of claims 58 or 59.

5

61. A computer program product comprising a computer readable recording medium having recorded thereon a computer program comprising code means for, when executed on a computer, instructing said computer to perform the steps of

10

receiving patient data in electronic form at a patient data controller unit;

storing said patient data in a patient database associated with said controller unit;

15

permitting access to said patient database in response to an authorised user command;

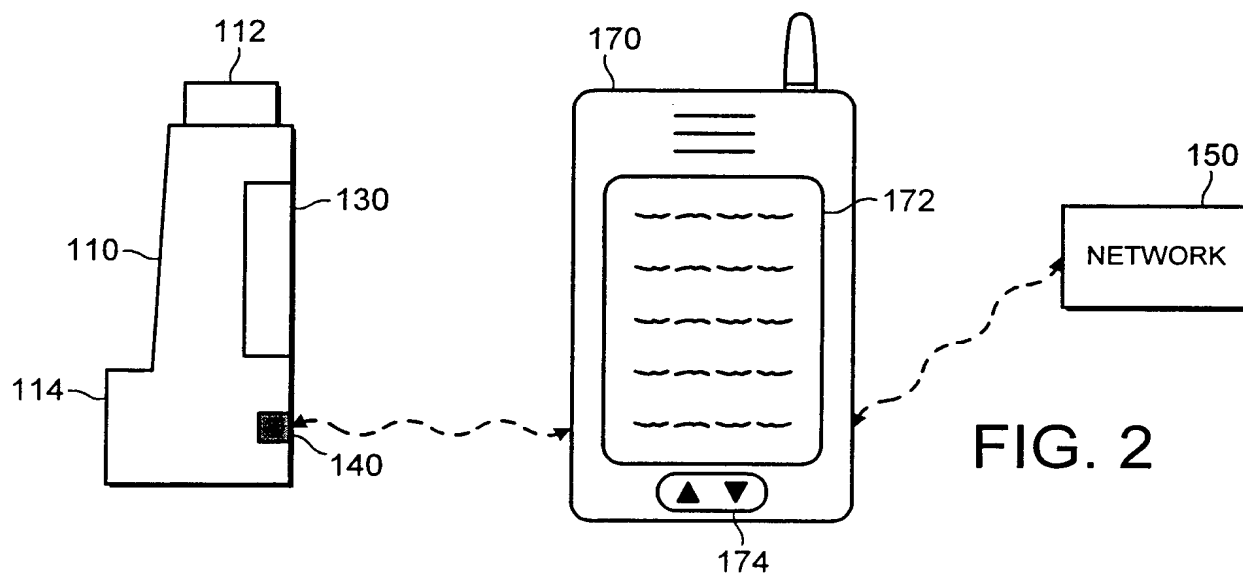
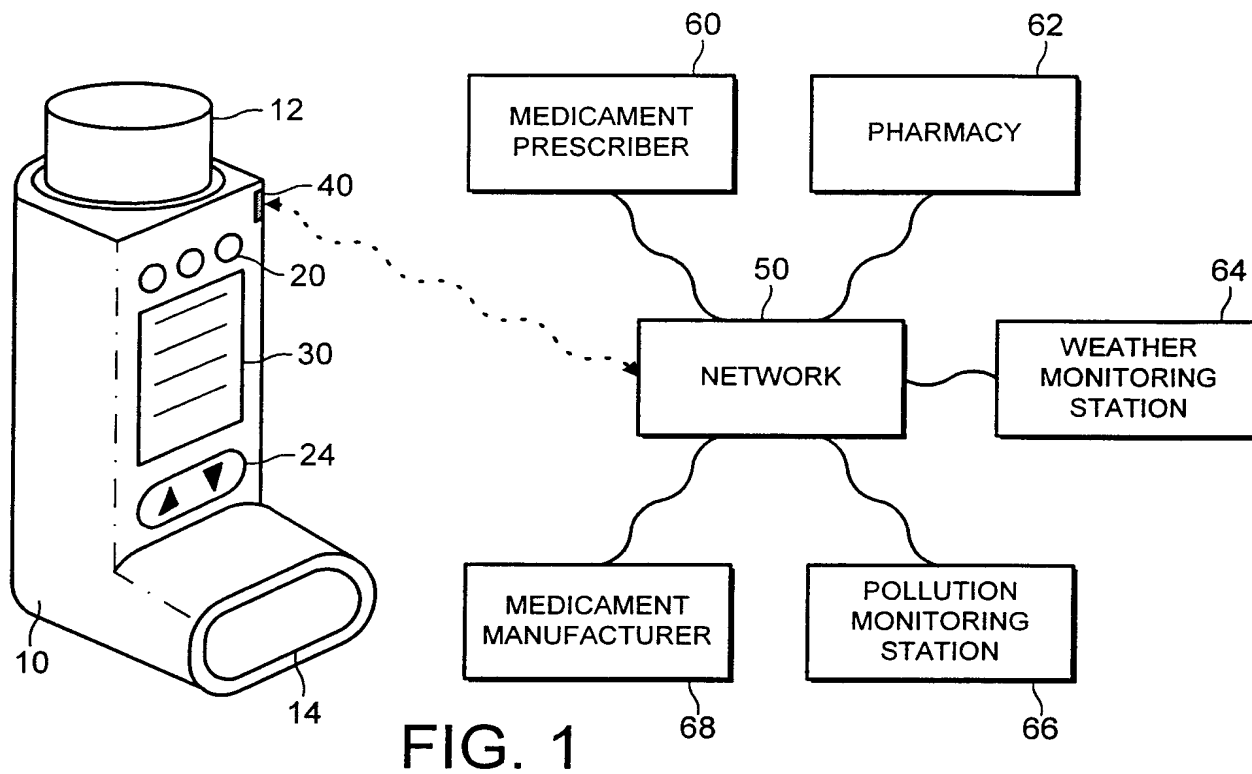
searching said patient database in response to an authorised user inquiry;

20

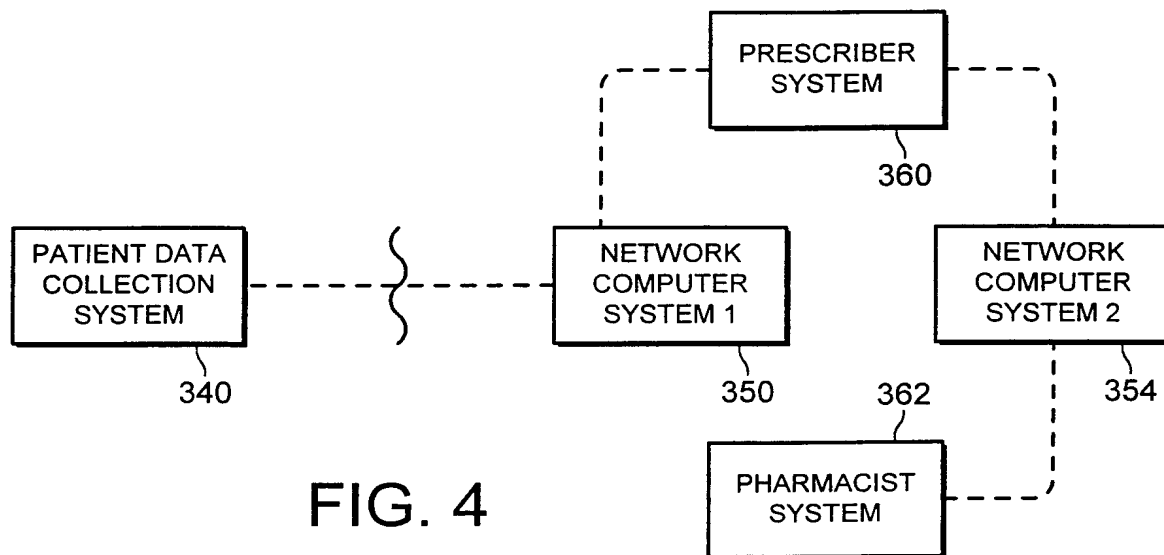
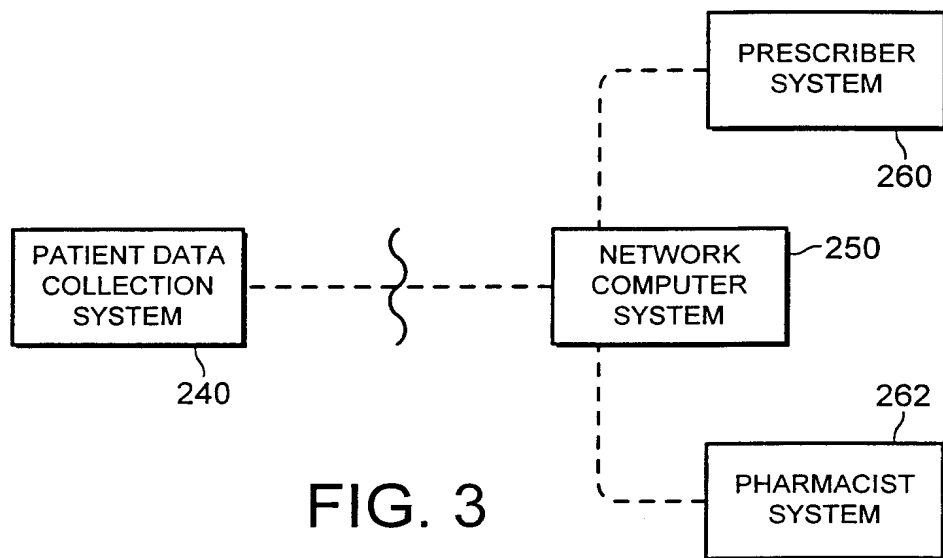
transmitting the results of said authorised user inquiry to the authorised user;

wherein the patient data and the authorised user inquiry originate remotely from the patient data controller unit.

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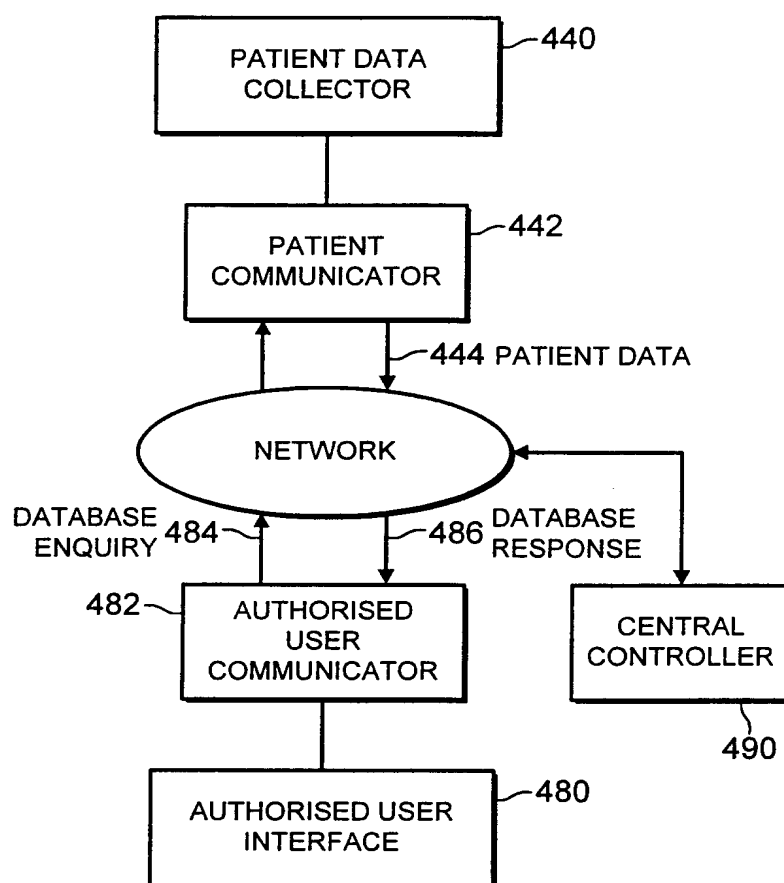


FIG. 5



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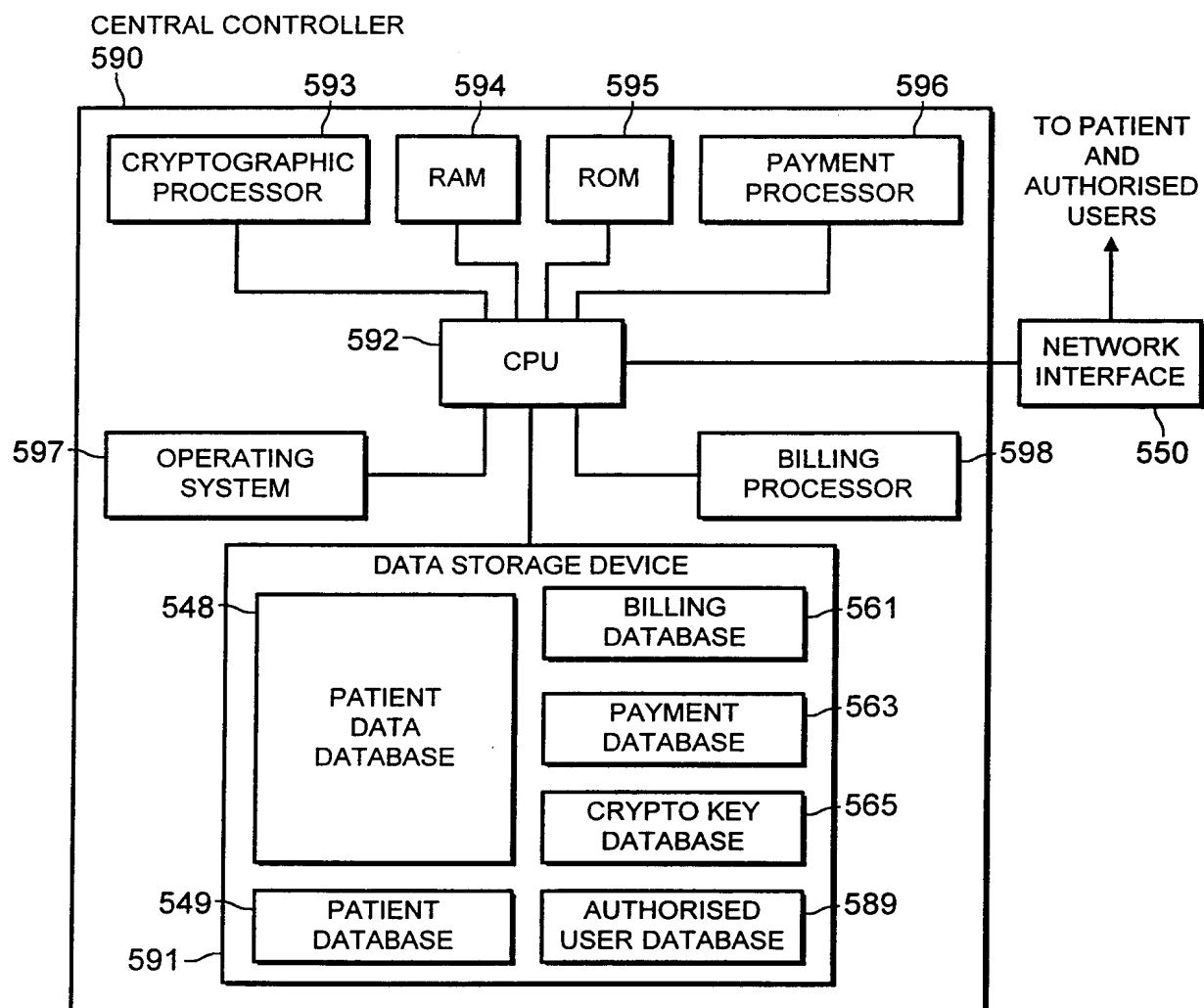


FIG. 6

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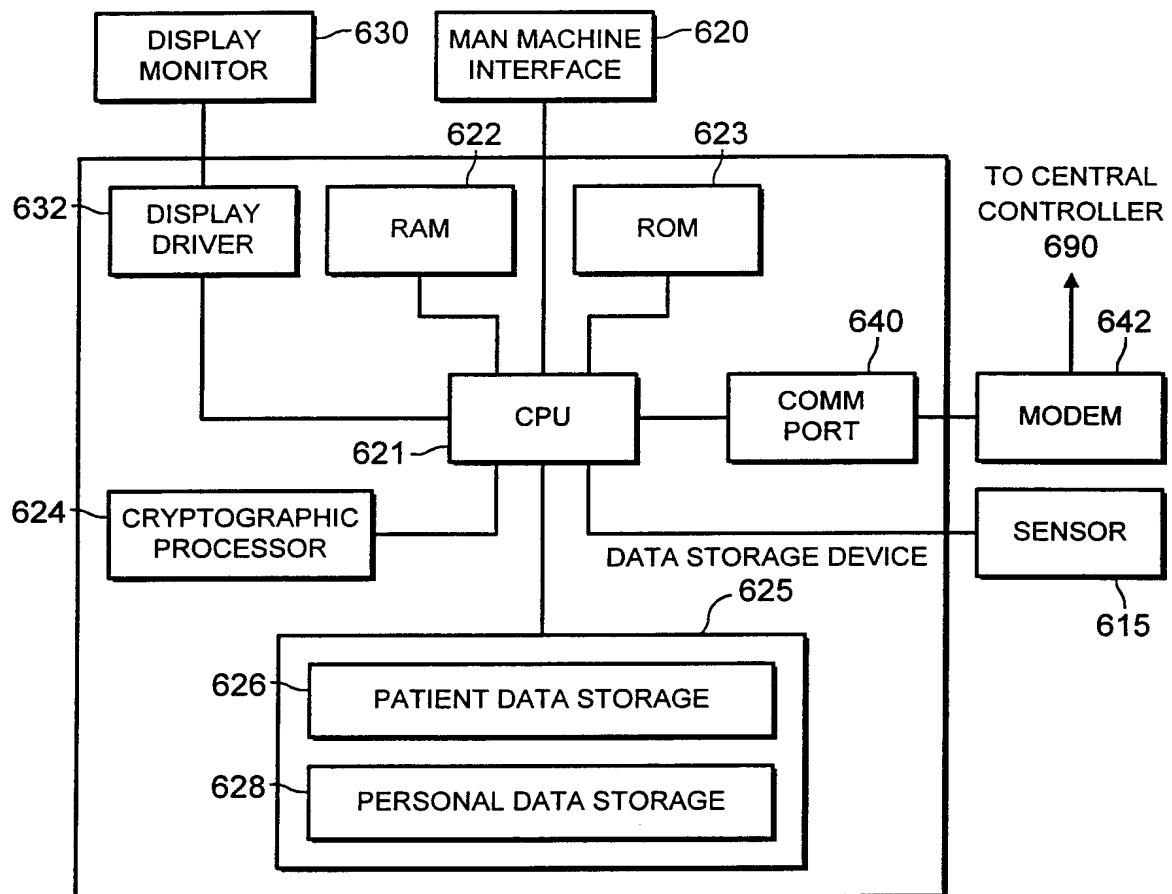


FIG. 7

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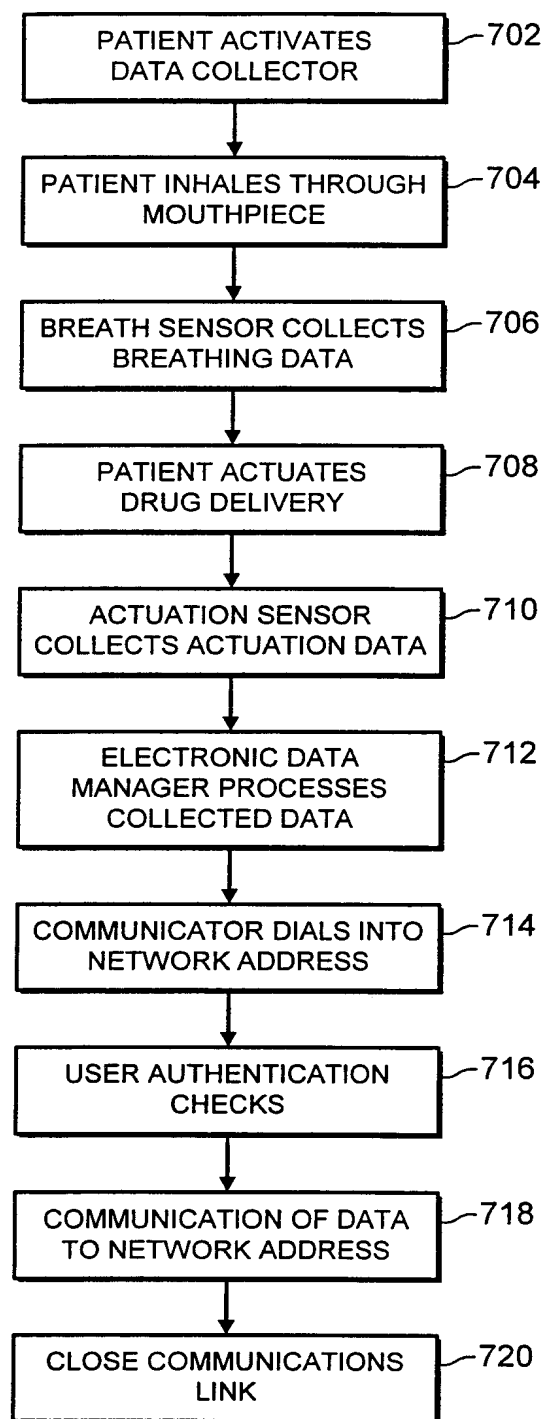


FIG. 8

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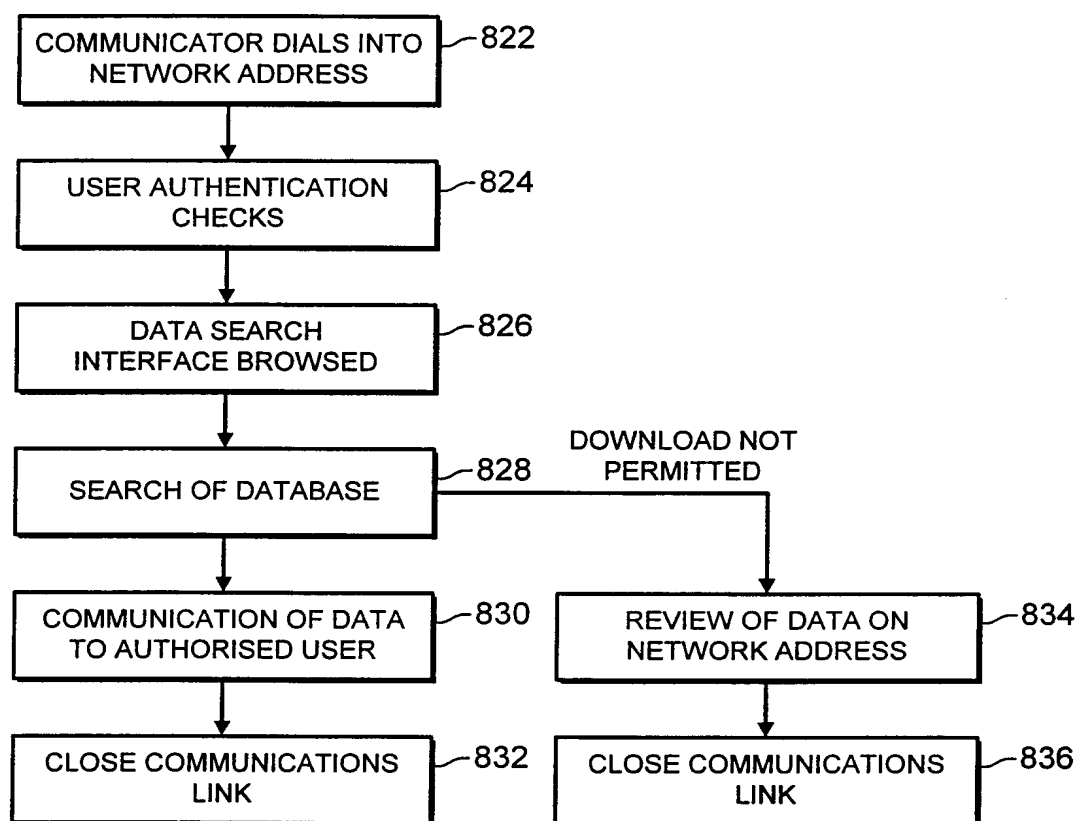


FIG. 9

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/09293

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G06F19/00 G06F1/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X          Y          A	US 5 924 074 A (EVANS JAE A) 13 July 1999 (1999-07-13)          column 4, line 64 -column 15, line 67 figures 1,4,13,14,24 ---  -/--	1-4, 9-15, 17-26, 29-31, 34, 47-55, 57-61 5-8, 35-46 16,27, 28,32, 33,56

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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\*G\* document member of the same patent family

Date of the actual completion of the international search

10 January 2001

Date of mailing of the international search report

17/01/2001

Name and mailing address of the ISA

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# INTERNATIONAL SEARCH REPORT

Int. Application No

PCT/EP 00/09293

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y A	WO 99 41682 A (JOHNSON DAVID WAYNE ;SOUTHERN RES INST (US); DEAN ALAN HOYT (US);) 19 August 1999 (1999-08-19)  page 3, line 16 -page 9, line 5 figures 1-3 ---	35-46  1-4, 9-34, 47-61
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